

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE  
(Rev. 2-32) PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.  
1146-4 DIV/CIP IISERIAL NO.  
09/916,858INFORMATION DISCLOSURE  
STATEMENT BY APPLICANTAPPLICANT  
Shults et al.

CONFIRMATION NO.

(Use several sheets if necessary)

FILING DATE  
July 27, 2001

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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
M	4,353,888	10/12/82	Sefton		11	
	4,431,004	02/14/84	Bessman et al.		11	
	4,436,094	03/13/84	Cerami		11	
	4,453,537	06/12/84	Spitzer		11	
	4,484,987	11/27/84	Gough		11	
	4,686,044	08/11/87	Behnke et al.		11	
	4,703,756	11/03/87	Gough et al.		11	
	4,757,022	07/12/88	Shults et al.		11	
	4,759,828	07/26/88	Young et al.		11	
	4,787,398	11/29/88	Garcia et al.		11	
	4,803,243	02/07/89	Fujimoto et al.		11	
	4,823,808	04/25/89	Clegg et al.		11	
	4,890,620	01/02/90	Gough		11	
	4,902,294	02/20/90	Gosserez		11	
	4,994,167	02/19/91	Shults et al.		11	
	5,165,407	11/24/92	Wilson et al.		11	
	5,190,041	03/02/93	Palti		11	
M	5,314,471	05/24/94	Brauker et al.		11	

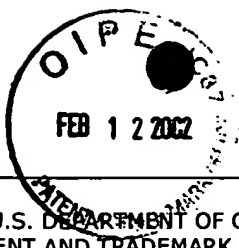
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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
Ngn	5,321,414	06/14/94	Alden et al.			
	5,322,063	06/21/94	Allen et al.			
	5,344,454	09/06/94	Clarke et al.			
	5,380,536	01/10/95	Hubbell et al.			
	5,390,671	02/21/95	Lord et al.			
	5,391,250	02/21/95	Cheney, II et al.			
	5,417,395	05/23/95	Fowler et al.			
	5,421,923	06/06/95	Clarke et al.			
	5,431,160	07/11/95	Wilkins			
	5,453,278	09/26/95	Chan et al.			
	5,462,064	10/31/95	D'Angelo et al.			
	5,469,846	11/28/95	Khan			
	5,476,094	12/19/95	Allen et al.			
	5,497,772	03/12/96	Schulman et al.			
	5,538,511	07/23/96	Van Antwerp			
	5,545,223	08/13/96	Neuenfeldt et al.			
	5,549,675	08/23/96	Neuenfeldt et al.			
	5,569,186	10/29/96	Lord et al.			

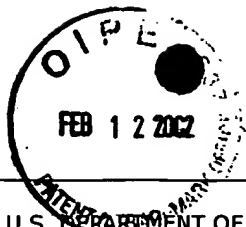
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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
m	5,569,462	10/29/96	Martinson et al.	11	11	
	5,578,463	11/26/96	Berka et al.	11	11	
	5,593,440	01/14/97	Brauker et al.	11	11	
	5,653,756	08/05/97	Clarke et al.	11	11	
	5,660,163	08/26/97	Schulman et al.	11	11	
	5,713,888	02/03/98	Neuenfeldt et al.	11	11	
	5,733,336	03/31/98	Neuenfeldt et al.	11	11	
	5,741,330	04/21/98	Brauker et al.	11	11	
	5,777,060	07/07/98	Van Antwerp	11	11	
	5,782,912	07/21/98	Brauker et al.	11	11	
	5,800,529	09/01/98	Brauker et al.	11	11	
	5,807,406	09/15/98	Brauker et al.	11	11	
	5,882,354	03/16/99	Brauker et al.	11	11	
	5,882,494	03/16/99	Van Antwerp	11	11	
	5,964,261	10/12/99	Neuenfeldt et al.	11	11	
	5,985,129	11/16/99	Gough et al.	11	11	
	6,001,067	12/14/99	Shults et al.	11	11	
	6,122,536	09/19/00	Sun et al	11	11	

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M	6,144,869	11/07/00	Berner et al.			
	6,175,752	01/16/01	Say et al.			
	6,180,416	01/30/01	Kurnik et al.			
	6,200,772	03/13/01	Vadgama et al.			
	6,201,980	03/13/01	Darrow et al.			
	6,208,894	03/27/01	Schulman et al.			
	6,212,416	04/03/01	Ward et al.			
	6,223,080	04/24/01	Thompson			
	6,223,083	04/24/01	Rosar			
	6,230,059	05/08/01	Duffin			
	6,233,471	05/15/01	Berner et al.			
	6,254,586	07/03/01	Mann et al.			
	6,256,522	07/03/01	Schultz			
	6,259,937	07/10/01	Schulman et al.			
	6,272,364	08/07/01	Kurnik			
	6,272,382	08/07/01	Faltys et al.			
M	6,299,578	10/09/01	Kurnik et al.			
	6,309,351	10/30/01	Kurnik et al.			

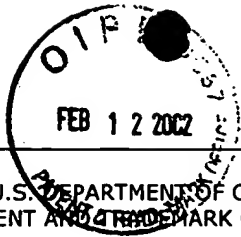
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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
~	6,326,160	12/04/01	Dunn et al.			
~	6,329,161	12/11/01	Heller et al.			

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	TRANSLATION	
						YES	NO
~	WO 90/00738	01/25/90	PCT				
	WO 92/07525	05/14/92	PCT				
	WO 92/13271	08/06/92	PCT				
	WO 93/19701	10/14/93	PCT				
	WO 94/22367	10/13/94	PCT				
	WO 96/01611	01/25/96	PCT				
	WO 96/32076	10/17/96	PCT				
	WO 96/36296	11/21/96	PCT				
	WO 01/20019	03/22/01	PCT				
	WO 01/20334	03/22/01	PCT				
	WO 01/34243	05/17/01	PCT				
	WO 01/58348	08/16/01	PCT				

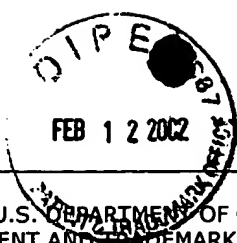
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FOREIGN PATENT DOCUMENTS

							TRANSLATION
m		WO 01/68901	09/20/01	PCT			
		WO 01/69222	09/20/01	PCT			
		WO 01/88524	11/22/01	PCT			
n		WO 01/88534	11/22/01	PCT			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

m		Updike et al., "Laboratory Evaluation of New Reusable Blood Glucose Sensor," <i>Diabetes Care</i> , 11:801-807 (1988).
		Moatti-Sirat et al., "Towards Continuous Glucose Monitoring: In Vivo Evaluation of a Miniaturized Glucose Sensor Implanted for Several Days in Rat Subcutaneous Tissue," <i>Diabetologia</i> 35:224-30 (1992).
		Armour et al., "Application of Chronic Intravascular Blood Glucose Sensor in Dogs," <i>Diabetes</i> 39:1519-26 (1990).
		Woodward, "How Fibroblasts and Giant Cells Encapsulate Implants: Considerations in Design of Glucose Sensor," <i>Diabetes Care</i> 5:278-281 (1982).
		Bindra et al., "Design and In Vitro Studies of a Needle-Type Glucose Sensor for Subcutaneous Monitoring," <i>Anal. Chem.</i> 63:1692-96 (1991).
n		Shults et al., "A Telemetry-Instrumentation System for Monitoring Multiple Subcutaneously Implanted Glucose Sensors," <i>IEEE Trans, Biomed. Eng.</i> 41:937-942 (1994).

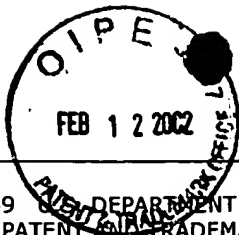
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GROUP

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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

NS		Phillips and Smith, "Biomedical Applications of Polyurethanes: Implications of Failure Mechanisms," <i>J. Biomat. Appl.</i> 3:202-227 (1988).
		Stokes, "Polyether Polyurethanes: Biostable or Not?," <i>J. Biomat. Appl.</i> 3:228-259 (1988).
		Urdike et al., "Enzymatic Glucose Sensors: Improved Long-Term Performance In Vitro and In Vivo," <i>Am.Soc. Artificial Internal Organs</i> 40:157-163 (1994).
		Urdike et al., "Implanting the Glucose Enzyme Electrode: Problems, Progress, and Alternative Solutions," <i>Diabetes Care</i> 5:207-21 (1982).
		Rhodes et al., "Prediction of Pocket-Portable and Implantable Glucose Enzyme Electrode Performance from Combined Species Permeability and Digital Simulation Analysis," <i>Anal. Chem.</i> 66:1520-1529 (1994).
		Tse and Gough, "Time-Dependent Inactivation of Immobilized Glucose Oxidase and Catalase," <i>Biotechnol. Bioeng.</i> 29:705-713 (1987).
		Gilligan et al., "Evaluation of a Subcutaneous Glucose Sensor Out to 3 Months in a Dog Model," <i>Diabetes Care</i> 17:882-887 (1994).
		McKean and Gough, "A Telemetry-Instrumentation System for Chronically Implanted Glucose and Oxygen Sensors," <i>IEEE Trans. Biomed. Eng.</i> 35:526-532 (1988).
		Shichiri et al., "Telemetry Glucose Monitoring Device with Needle-Type Glucose Sensor - A Useful Tool for Blood Glucose Monitoring in Diabetic Individuals," <i>Diabetes Care</i> 9:298-301 (1986).
NS		Lyman, "Polyurethanes. I. The Solution Polymerization of Diisocyanates with Ethylene Glycol," <i>J. Polymer Sci.</i> 45:49 (1960).

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M		DuPont <sup>1</sup> Dimension AR <sup>®</sup> (Catalog).
		Direct 30/30 <sup>®</sup> meter (Markwell Medical) (Catalog).
		Fischer et al., "Oxygen Tension at the Subcutaneous Implantation Site of Glucose Sensors," <i>Biomed. Biochem.</i> 11/12, 965-972 (1989).
		Brauker et al., "Neovascularization of Synthetic Membranes Directed by Membrane Microarchitecture," <i>Journal of Biomedical Materials Research</i> 29:1517 (1995).
		Abstract presented by James Brauker, Ph.D., "Neovascularization of Cell Transplantation Devices: Membrane Architecture-Driven and Implanted Tissue-Driven Vascularization," Baxter Healthcare Corp.
n		Brauker et al., "Local Inflammatory Response Around Diffusion Chambers Containing Xenografts", <i>Transplantation</i> , Vol. 61, 1671-1677, No. 12, June 27, 1996.

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